

APR 25 2014

8. 510(k) Summary

CDC hereby submits this Special 510(k) in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter

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Proprietary Name

CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel, Influenza B Lineage Genotyping Kit

Common or Usual Name

Influenza B Lineage Genotyping Kit

Regulatory Information

Classification Regulation Section: 866.3980- Respiratory viral panel multiplex nucleic acid assay
Classification: Class II
Classification Product Code: OZE
Subsequent Product Codes: NSU
Panel: Microbiology

Predicate Device

CDC Human Influenza Virus Real-time RT-PCR Diagnostic Panel (K132508)

Device Description

The Influenza B Lineage Genotyping Kit contains components of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel that is used in real-time RT-PCR (rRT-PCR) assays on the ABI 7500 Fast Dx Real-Time PCR Instrument. The Influenza B Lineage Genotyping Kit consists of oligonucleotide primers and dual-labeled hydrolysis (TaqMan[®]) probes to be used in rRT-PCR for the *in vitro* qualitative detection and characterization of human influenza viruses from viral RNA in respiratory specimens from patients presenting with influenza-like illness (ILI). The Influenza B Lineage Genotyping Kit is based on technology which is used in many molecular diagnostic assays.

rRT-PCR assays are one-tube assays that first reverse-transcribe specific regions of RNA into cDNA copies. The cDNA then serves as a template for a polymerase chain reaction that utilizes a thermocyclic heating and cooling of the reaction to logarithmically amplify a specific region of DNA. The probe anneals to a specific internal target sequence located between the target loci of the forward and reverse primers. During the extension phase of the PCR cycle, the 5' nuclease activity of Taq polymerase degrades any probe molecules hybridized to amplified target sequence, causing the reporter dye to separate from the quencher dye, and generating a fluorescent signal. With each cycle, additional reporter dye molecules are cleaved from their respective probes, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle. Amplification of targets is reflected by logarithmic increase in fluorescence over time in comparison to the background signal.

Intended Use

The Influenza B Lineage Genotyping Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in real-time RT-PCR (rRT-PCR) assays on an Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR instrument in conjunction with clinical and epidemiological information:

- For the determination of the genetic lineage of human influenza B viruses as B/Victoria or B/Yamagata lineage from viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs [NPS], nasal swabs [NS], throat swabs [TS], nasal aspirates [NA], nasal washes [NW], and dual nasopharyngeal/throat swabs [NPS/TS]) from human patients with signs and symptoms of respiratory infection and/or from viral culture;
- To provide epidemiologic information for surveillance of circulating influenza viruses.

Performance characteristics for influenza B lineage genotyping were established during a season when influenza B/Victoria and B/Yamagata lineages were found in approximately equal proportion.

Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

All users, analysts, and any person reporting results from use of this device should be trained to perform and interpret the results from this procedure by a competent instructor prior to use. CDC Influenza Division will limit the distribution of this device to only those users who have successfully completed a training course provided by CDC instructors or designees.

Technological Characteristics

The changes proposed to the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel subject to this special 510(k) are for labeling purposes only and will not alter the technological attributes of the device.

Substantial Equivalence Comparison

The CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel (K132508) will serve as the predicate for the intended change. Please see Table 1 for a detailed comparison.

Table 1: Device Comparison

	CDC Human Influenza Virus Real-time PCR Diagnostic Panel (K132508)	Influenza B Lineage Genotyping Kit
Intended Use	<p>The CDC Human Influenza Virus Real-Time PCR Diagnostic Panel is intended for use in Real-time RT-PCR assays on an Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument in conjunction with clinical and epidemiological information:</p> <ul style="list-style-type: none"> For qualitative detection of influenza virus type A or B from viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes and dual nasopharyngeal/throat swabs); and lower respiratory tract specimens (including bronchoalveolar lavages, bronchial washes, tracheal aspirates, sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture; For determination of the subtype of seasonal human influenza A virus as seasonal A/H1N1, A/H1N3, and/or A/H1N1pdm09 from viral RNA in upper respiratory tract clinical specimens (including nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes and dual nasopharyngeal/throat swabs); and lower respiratory tract specimens (including bronchoalveolar lavages, bronchial washes, tracheal aspirates, sputum, and lung tissue) from human patients with signs and symptoms of respiratory infection and/or from viral culture; For the determination of the genetic lineage of human influenza B viruses as B/Victoria or B/Yamagata lineage from viral RNA in upper respiratory tract clinical specimens (including NPS, NS, TS, NA, NW, and NPS/TS) from human patients with signs and symptoms of respiratory infection and/or from viral culture; For the presumptive identification of virus in patients who may be infected with influenza A subtype A/H15(Asian Lineage) from viral RNA in human respiratory specimens and viral culture in conjunction with clinical and epidemiological risk factors; To provide epidemiologic information for surveillance of the circulating influenza viruses. <p>Performance characteristics for influenza were established during a season when seasonal influenza viruses A/H1N1 and A/H3N2 were the predominant influenza A viruses in circulation and during a season when the A/H1N1pdm09 influenza virus was the predominant influenza A virus in circulation. Performance characteristics may vary with other emerging influenza A viruses.</p> <p>Testing with the influenza H5a and H5b primer and probe sets should not be performed unless the patient meets the most current U.S. Department of Health and Human Services (DHHS) clinical and epidemiological criteria for testing suspect A/H15 specimens. The definitive identification of influenza A/H15 (Asian lineage) either directly from patient specimens or from virus cultures requires additional laboratory testing, along with clinical and epidemiological assessment in consultation with national influenza surveillance experts.</p>	<p>The Influenza B Lineage Genotyping Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel and is intended for use in Real-time RT-PCR assays on an Applied Biosystems (ABI) 7500 Fast Dx Real-Time PCR Instrument in conjunction with clinical and epidemiological information:</p> <ul style="list-style-type: none"> For the determination of the genetic lineage of human influenza B viruses as B/Victoria or B/Yamagata lineage from viral RNA in upper respiratory tract clinical specimens (including NPS, NS, TS, NA, NW, and NPS/TS) from human patients with signs and symptoms of respiratory infection and/or from viral culture; To provide epidemiologic information for surveillance of the circulating influenza viruses. <p>Performance characteristics for influenza B lineage genotyping were established during a season when influenza B/Victoria and B/Yamagata lineages were found in approximately equal proportion.</p> <p>Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.</p>

New Special 510(k)

CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel, Influenza B Lineage Genotyping Kit

	CDC Human Influenza Virus Real-time PCR Diagnostic Panel (K132508)	Influenza B Lineage Genotyping Kit
Intended Use (Cont'd)	<p>Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.</p> <p>If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted unless a BSL 3+ facility is available to receive and culture specimens.</p>	
Specimen Types	Nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes and dual nasopharyngeal/throat swabs, bronchoalveolar lavages, bronchial aspirates, bronchial washes, tracheal aspirates, sputum, and lung tissue. Only upper respiratory specimens for influenza B genetic lineage determination	Only upper respiratory specimens for influenza B genetic lineage determination. Nasopharyngeal swabs, nasal swabs, throat swabs, nasal aspirates, nasal washes and dual nasopharyngeal/throat swabs.
Technology	Real-time RT-PCR	Same
Required Instrumentation	Applied Biosystems 7500 Fast Dx Real- Time PCR Instrument with SDS software version 1.4	Same
Organism Detected	Universal influenza A viruses (animal and human). Swine-origin influenza A viruses, Influenza B viruses. Influenza A subtypes: seasonal A/H1, A/H3, A/H1pdm09, and A/H5, Influenza B/Yamagata and B/Victoria lineages	Influenza B/Yamagata and B/Victoria lineages
Nucleic Acid Extraction	Yes	Same

Risk Analysis

The Influenza B Lineage Genotyping Kit contains reagents and controls of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel. A risk analysis of the labeling modification to create a separate Package Insert for the Influenza B Lineage Genotyping Kit was performed to verify that the change in the package insert did not present increased or new risks to the user. No new significant risks were identified as a result of the proposed modification.

Substantial Equivalence Conclusion

The changes proposed to the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel do not alter the device's design or technological attributes. In addition, the indications for use and intended use of the CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel will remain the same. The modification to the package insert included with the Influenza B Lineage Genotyping Kit made available to users retains all required label information, and is determined to be substantially equivalent to the predicate.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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April 25, 2014

Re: K140857

Trade/Device Name: CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel,
Influenza B Lineage Genotyping Kit

Regulation Number: 21 CFR 866.3980

Regulation Name: Respiratory viral panel multiplex nucleic acid assay

Regulatory Class: II

Product Code: OZE, NSU

Dated: April 02, 2014

Received: April 03, 2014

Dear Dr. Yu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act): 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Uwe Scherf -S for

Sally Hojvat, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics and Radiological
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Enclosure

Indications for Use

510(k) Number (if known): K140857

Device Name: CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel, Influenza B Lineage Genotyping Kit

Indications For Use:

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Prescription Use <u> X </u> (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use <u> </u> (21 CFR 801 Subpart C)
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Concurrence of Center for Devices and Radiological Health (CDRH)

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